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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/628,667 | 07/28/2000 | David Putnam | 10436-0010-999 | 3663 |

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GAINESVILLE, FL 32606-6669

EXAMINER

EPPERSON, JON D

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1639

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 09/628,667 | Applicant(s) PUTNAM ET AL. | |
| | Examiner Jon D Epperson | Art Unit 1639 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 136-171 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 136-171 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. <u>8/5/2004</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

SUBSTITUTE ELECTION OF SPECIES

1. The Response filed May 19, 2004 is acknowledged.
2. Upon further review of Applicants' newly added claims (e.g., see 5/19/2004 Response wherein claims 136-171 were added), an additional election of species was deemed necessary (see below).
3. Please note that this action replaces all previous election of species requirements. However, the restriction requirements set out in Paper No. 7 remain in effect (e.g., see Paper No. 7, paragraph 1 wherein 10 patentably distinct groups were set forth).

Election/Restriction

4. Upon review of the instant case, the application was deemed to contain claims directed to patentably distinct species of the claimed invention. Election from the following species is required. Note: applicant must elect *one* species from *each* subgroup below. Claim 180 is generic

Subgroup 1: Species of component-in-common (see claims 136)

Applicant must elect, for the purposes of search, a *single species* of component-in-common wherein a *specific structure* is set forth, which clearly shows all of the atoms and bonds that are necessary to define said component-in-common i.e., only **ONE** component-in-common should be elected (e.g., see figure 3A wherein griseofulvin is disclosed; see also Example 1). Applicant should *not* use notations like X or R when identifying the elected structure because these letters represent groups with variable members and, as a result, more than one species would be erroneously elected. Applicants must also indicate whether the elected component-in-common has is an "active" or "inactive" component (e.g., see claim 139), a "pharmaceutical" (e.g., see claim 140), a "therapeutic" or "prophylactic"

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or “diagnostic” agent (e.g., see claim 141), a “solid” or a “liquid” (e.g., see claims 143-144).

Subgroup 2: Species of additional component (see claims 136, 171-172)

Applicant must elect, for the purposes of search, a single species of additional component wherein a specific structure is set forth, which clearly shows all of the atoms and bonds that are necessary to define said additional component i.e., only ONE additional component should be elected (e.g., see Table 2, wherein SDS is disclosed). Applicant should not use notations like X or R when identifying the elected structure because these letters represent groups with variable members and, as a result, more than one species would be erroneously elected. Applicants must also indicate whether the elected additional components is an excipient or not (e.g., see claim 155) and if so what class of excipient it is (e.g., see claims 171-172 wherein acidulent, solubilizing component, etc. are disclosed). Applicants should NOT elect a broad class of additional components like “acidulent” without elected a specific compound (i.e., ONE compound) that falls within this class.

Subgroup 3: Species of analysis (e.g., see claims 136)

Applicant must elect, for the purposes of search, a single species of analysis (e.g., see specification, page 37, line 11 wherein UV spectrophotometer analysis).

Subgroup 4: Species of property to generate a data set (e.g., see claims 136)

Applicant must elect, for the purposes of search, a single species of property to generate a data set (e.g., see specification, page 10, line 13 wherein solubility is disclosed).

Subgroup 5: Species of interaction between components (e.g., see claims 137)

Applicant must elect, for the purposes of search, a single species of interaction between components (e.g., see claim 137 decrease solubility).

Subgroup 6: Species of input (e.g., see claims 148-149)

Applicant must elect, for the purposes of search, a single species of input i.e., “solid” form or “liquid” form.

Subgroup 7: Species of data mining software (e.g., see claims 148-149)

Applicant must elect, for the purposes of search, a single species of data mining software (e.g., MATLAB). In addition, Applicants must elect a specific algorithm (e.g., see claim 153).

Subgroup 8: Species of automated robotics system (e.g., see claims 148-149)

Applicant must elect, for the purposes of search, a single species of automated robotics system (e.g., see page 34, line 32 wherein the TECAN automated liquid pipetting system is disclosed).

5. **Please Note:** Applicants must disclose which claims read on the elected species (see paragraphs 8 and 9 below).

6. The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

7. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

8. Applicant is advised that a reply to this requirement **must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.** An

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argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

13. Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.
August 6, 2004

BENNETT CELSA
PRIMARY EXAMINER


